UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/694,190	10/28/2003	Lloyd Wolfinbarger JR.	95176562-003002 (64230-00	3910

7590 10/04/2006

EXAMINER
FORD, ALLISON M

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/04/2006

Baker & McKenzie
Pennzoil Place, South Tower
Suite 3400
711 Louisiana
Houston, TX 77002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/694,190	WOLFINBARGER ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-46, drawn to a first process for devitalizing soft tissue, classified in class 435, subclass 380.

II. Claims 47-59, drawn to a devitalized soft tissue graft, classified in class 424, subclass 422.

III. Claims 60-66, drawn to a second process for devitalizing soft tissue, classified in class 435, subclass 378.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and III are directed to distinct processes for devitalizing soft tissue. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed involve distinct steps that render the methods non-obvious over one another, for example, the method of invention I requires treatment with an extraction solution and decontaminating agents, the method of invention III does not require such treatments steps. Alternatively, the method of invention III requires either an "extensive devitalization method" or a "non-extensive devitalization method" depending on the intended use of the tissue; the method of invention I does not describe either of such processes. The claims included in Group III do not specify what specific steps are included in either the 'extensive devitalization method' or 'non-extensive devitalization method' so it cannot be assumed or concluded that either of the methods are overlapping in scope with the method of invention I, and as such restriction between the inventions is proper.

Invention I and III are related to invention II as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case it appears both the methods of inventions I and III can effectively be produce the devitalized tissue as claimed in invention II. It is noted that claims 56, 57 and 59 specify the tissue graft (product) is made by the process of claims 1 or 2; however these claims are considered to be product by process claims, in such cases the process of making the product is only considered as far as it affects the final product, as claimed, in the case of claims 56, 57 and 59 the product, as claimed, is a devitalized soft tissue graft, with no defining features or characteristics that would show it cannot be produced by the method of invention III. Thus, the product of invention II is not inherently linked to either method, but rather can be made by multiple, materially distinct processes, and restriction is proper.

Therefore, a search and examination of all inventions in one patent application would result in an undue burden. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classifications, and a search for one group does not require a search for another group, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, which ever is earlier. Amendments

submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in the light of *In re Ochiai, In re Brouwer* and 34 U.S.C § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The following SIX (6) elections of specie are further required. A single species must be elected from EACH of the following SIX groups, for a total of SIX specie elections:

1. Type of endonuclease:

Claims 1, 2 and 5 are generic to a plurality of species of endonucleases which may be employed in the method of claims 1 and 2, the species are as follows:

a) BENZONASE; b) PULMAZYME (both from claim 8)

2. Type of decontaminating agent:

Claims 1, 2, 19, 20, 23 and 24 are generic to a plurality of species of decontaminating agents which may be employed in the method of claims 1 and 2, the species are as follows:

c) an antimicrobial agent; d) an alcohol; c) chlorine dioxide; d) polyethyleneimine; e) ethanol; f) isopropanol; g) methanol; h) glycerol; I) methylparaben; j) an antibiotic; k) adonitol; l) sorbitol; m) ribitol; n) galactitol; o) D-galactose; p) 1, 3, dihydroxypropanol; q) ethylene glycol; r) triethylene glycol; s) propylene glycol; t) glucose; u) sucrose; v) mannitol; w) xylitol; x) meso-erythritol; y) adipic acid; z) proline; aa) hydroxyproline (from claims 19 and 24)

3. Type of water-replacement agent:

Claims 1, 2, and 21 are generic to a plurality of species of water replacement agents which may be employed in the method of claims 1 and 2, the species are as follows:

bb) polyol family; cc) monoglycerides; dd) monoolein; ee) monolinolein; ff) various short and long chain free fatty acids and their corresponding monoacylglycerol esters; gg) glycerol; hh) adonitol; ii) sorbitol; jj) ribitol; kk) galactitol; ll) D-galactose; mm) 1, 3, dihydroxypropanol; nn) ethylene glycol; oo) triethylene glycol; pp) propylene glycol; qq) glucose; rr) sucrose; ss) mannitol; tt) xylitol; uu) meso-erythritol; vv) adipic acid; ww) proline; xx) hydroxyproline; yy) "similar water-soluble small molecular weight that can be expected to replace water in the base matrix structure of soft tissue and provide the hydrating functions of water in the tissue" (from claim 21

4. Type of non-denaturing detergent:

Claims 1, 2, and 28 are generic to a plurality of species of non-denaturing detergents which may be employed in the method of claims 1 and 2, the species are as follows:

zz) N-lauroyl sarcosinate; aaa) deoxychloic acid; bbb) taurocholic acid; ccc) glycocholic acid; ddd) cholic acids (all from claim 28)

5. Type of storage solution:

Claims 1, 2 and 22 are generic to a plurality of species of storage solutions which can be employed in the methods of claim 1 and 2, the species are as follows:

eee) ultrapure, endotoxin free water; fff) a water replacement agent (subject to species election from Group 3 above) (both from claim 22)

6. Type of tissue included with soft tissue graft:

Claims 51-55 recite a plurality of additional tissue types that are to be included ('further comprising') with the devitalized tissue graft of claim 50, the species are as follows:

ggg) a vein ; hhh) an artery ; iii) a heart valve; jjj) a ligament; kkk) a tendon; lll) fascia; mmm) dura mater; nnn) meniscus; ooo) pericardium; ppp) skin (from claims 51-55)

Each of the elections of specie set forth above have been required because a search of each and every species in each group would constitute an undue burden on the examiner. The different species of within each 'genus' listed above do not constitute patentably distinct inventions. The fact that at least original claims 1, 2 or 50 are generic is the precise reason for the requirement for specie elections; in the interest of expedient processing of applications, the examiner concentrates on the patentability of the entire invention as it pertains to one species. Once the invention *per se* is claimed in an allowable manner, all disclosed species are rejoined to the claims.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of the above SIX groups, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651